II. REMARKS:

A. Status of the Claims

Claims 1-8 were originally filed with the case on June 2, 2005. A Restriction Requirement mailed on April 15, 2008, stated that the originally filed claims were directed to two patentably distinct inventions. According to the Restriction Requirement, Group I (Claims 1-4) is directed to a method of treating glaucoma and Group II (Claims 5-8) is directed to a composition comprising at least one cathepsin K antagonist. In a Response to Restriction Requirement filed on September 15, 2008, Applicants elected the invention of Group I, that is, claims 1-4. The outstanding Office Action, mailed on November 26, 2008, incorrectly states that only claims 1-2 remain pending and that claims 3-8 are withdrawn from consideration. Claims 1 and 4 are amended, claim 2 is cancelled and claims 5-8 are withdrawn from consideration herein. No claims are added. Support for the amendments can be found throughout the specification and claims as originally filed. It is believed that claims 1-4 remain pending.

B. The Claims are Supported by Written Description

The Action rejects claim 1 under Section 112, first paragraph, as failing to comply with the written description requirement. The Action asserts that claim 1 is directed to a compound defined by reference to desirable characteristics or properties, i.e., cathepsin K antagonism. The Action takes the position that, in order to adequately describe a genus, one must include distinguishing identifying characteristics, and that the "claims effectively read on any and all biological chemical compounds." Applicants respectfully traverse.

It is submitted that to state that "the claims effectively read on any and all biological chemical compounds," appears to be a gross overstatement of the scope of the claims. The claims, as originally filed, were directed to all compounds having cathepsin K antagonist activity. The skilled artisan is well aware that not all compounds in existence do not have cathepsin K antagonist activity. Furthermore, the specification clearly explains that additional inhibitors of cathepsin K may be identified by using enzyme assays with a known small peptide fluorogenic substrate for cathepsin K, and identifies the cleavable fluorogenic peptide Z-Phe-Arg-AMC as an appropriate substrate. In fact, the specification even identifies a source for the substrate (Bachem Biosciences, Inc.). (See Spec. page 17, lines 22-28). Such assays are well known and routine to the skilled artisan.

Section 112 requires simply that the patent applicant provide a disclosure which sufficiently enables one skilled in the art to carry out the invention commensurate with the scope of the claims. *Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1213, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). It is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 858 F.2d 731, 735, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). In fact, it is preferable that what is well known in the art be omitted from the disclosure. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) (citing *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984)). It is submitted that the Applicants have met the requirements of § 112.

The Action further argues that, because there are known screening methods for the identification of cathepsin K antagonistic activity, Applicant would not be in possession of the myriad of compounds embraced by the claims. It is not a requirement of the patent law

as it relates to chemical application that Applicants identify, or even ascertain, all compounds that might fall within an identified genus. What is required is that the skilled artisan have an objective belief that the specification teaches how to make and use the claimed invention in its full scope without "undue experimentation." *In re Wright*, 999 F.2d 1557, 1560 (Fed. Cir. 1993). Applicants have shown that compounds having cathepsin K antagonist activity can be used to treat glaucoma and have provided a large number of examples of such compounds. Therefore, it is submitted that the skilled artisan would objectively and reasonably believe that any compound having cathepsin K antagonist activity would be useful in the methods of the invention.

Notwithstanding the foregoing, it is believed that the amendments to claim 1 render the written description rejection moot. Therefore, Applicants respectfully request withdrawal of the written description rejection.

C. The Claims are Definite

Next, the Action rejects claim 2 under Section 112, second paragraph, as being indefinite for failing to particularly point out the subject matter of the invention. The Action asserts that the term "derivative" in the claim is indefinite and it is unclear what is encompassed by the term. It is believed that the definiteness rejection based upon the term "derivative" is moot in light of the amendments to the claims. Therefore, Applicants respectfully request that the definiteness rejection based upon the term "derivative" be withdrawn.

D. The Claims are Definite

Next, the Action again rejects claim 2 under Section 112, second paragraph as being indefinite for failing the particularly point out the subject matter of the invention. The Action argues that use of certain names, such as AC-3-1, AC-3-3, and SB-357114, to identify compounds for use in the methods of the present invention, is indefinite. Applicants have amended the claims to include the compound names or structures for compounds identified using "lab designations." The compound names for these compounds can be found in the literature, for example, in Koshihara *et al.* BIOCHEM. PHARM. 37:2161-2165 (1988). Therefore, Applicants respectfully request that the definiteness rejection based upon the use of "lab designations" be withdrawn.

E. The Claims are Not Anticipated by Banerjee

Finally, the Action rejects claims 1-2 under Section 102(a) and 102(e) as being anticipated by Banerjee (U.S. Patent Pub. 2002/0160979). Banerjee is said to teach a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions disclosed in Banerjee are said to include neovascular glaucoma. Applicants respectfully traverse.

The present invention is directed to a method for lowering intraocular pressure by administering to the eye of a patient a composition containing a cathepsin K antagonist. Elevated intraocular pressure associated with glaucoma is not associated with angiogenesis. Moreover, neovascular glaucoma is not typically associated with elevated intraocular pressure.

It is believed that elevated levels of cathepsin K function to destroy extracellular matrix required for normal filtration and cellular function in the trabecular meshwork (TM). Banerjee does not discuss the use of cathepsin K antagonists to lower intraocular pressure. The skilled artisan would not look to the art related to treatment of angiogenesis when seeking a solution to treating elevated intraocular pressure because the cause of the damage to the tissues (i.e., elevated intraocular pressure vs. oxidative stress) and the tissues affected (i.e., inner retinal tissues vs. outer retinal tissues) differ significantly.

It is well settled that, for a prior art reference to render a claim anticipated, that reference must set forth every element in the claim, either expressly or inherently. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983)). In other words, to support a rejection under section 102, a reference must show ***all*** features of the rejected claim(s). *Minnesota Mining & Mfg. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1569, 24 USPQ2d 1321 (Fed. Cir. 1992). The Federal Circuit has stated that "absence of a claim element from a prior art reference negates anticipation." *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 U.S.P.Q. 409 (Fed. Cir. 1984). Since Bannerjee lacks a teaching of lowering intraocular pressure, it cannot be said to anticipate the claimed invention.

In light of the foregoing arguments, Applicants respectfully request that the anticipation rejection based on Bannerjee be withdrawn.

F. Conclusion

This is submitted to be a complete response to the outstanding Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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